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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,438	MCCROSKEY ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 8, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-48* is/are rejected.

7)☒ Claim(s) *35-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *January 31, 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on December 8, 2005 is entered.

Currently, claims 35-48 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively starting with the number following the highest numbered claims previously presented. Specifically, Applicants cancelled claims 35-40 in the response filed January 14, 2005. Newly submitted claims 35-48 should be renumbered 41-54 in future correspondence.

Claim Rejections - 35 USC § 112 – first paragraph

Claims 35-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, Examiner is unable to locate antecedent support for the following claim limitations in the specification, as originally filed:

In claim 35:

The step of binding a glycated protein to "negatively charged groups"

The step of binding a nonglycated protein to "negatively charged groups"

The step of binding a glycated protein and a nonglycated protein to "negatively charged groups"

The step of removing nonglycated protein from "negatively charged groups"

The step of removing glycated protein from "negatively charged groups"

The step of removing both nonglycated protein and glycated protein from "negatively charged groups"

The negative limitation "without an incubation period"

In claim 46:

The R group *comprising* "phenyl, phenyl, alkyl of 1-6 carbons, ethyl, 1-propyl, 3-methyl-1-butyl or aminophenyl"

Claim Rejections - 35 USC § 112 – second paragraph

Claims 35-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 35, the recitation of the pronoun "that", as in "*that* are capable of binding both the glycated and the nonglycated forms", is indefinite. The identity of object(s) referenced by "that" is not clear. Whether "that" references "solid support" and/or "negatively charged groups" is not clear.

In claim 35, the recitation of the term "thereon", as in "having hydroxylboryl groups *thereon*", is indefinite. The identity of location(s) referenced by "thereon" is not clear. Whether "thereon" references "solid support" and/or "glycated" protein and/or "nonglycated" protein is not clear.

In claim 35, the recitation of the pronoun "that", as in "*that* are capable of binding the glycated form" is indefinite. The identity of object(s) referenced by "that" is not clear. Whether "that" references "hydroxyboryl groups" and/or "negatively charged groups" is not clear.

In claim 35, the recitation of the infinitive "to remove" is indefinite. Whether the act or process of removing is completed or performed, or merely intended, is not clear.

In claim 35, the recitation of the term "whereupon" is indefinite. The identity of object(s), location(s), event(s) and/or condition(s) precedent referenced by "whereupon" is not clear.

In claim 47, the recitation of the phrase "is selected from the group carboxylate..." is indefinite. Whether a Markush-type claim is intended is not clear.

In claim 46, the duplicate recitation of "phenyl" is indefinite.

In claim 48, the recitation of the phrase "is selected from the group of cellulose..." is indefinite. Whether a Markush-type claim is intended is not clear.

Claim Rejections - 35 USC § 103

Claims 35-38 and 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu & Pawliszyn (US 5,985,121) in view of Murel (US 4,925,545).

Wu & Pawliszyn describe a method for quantitating a glycated protein (see Fig. 3, "A_{1c}") in a sample (see col. 4, line 17, "protein samples"), wherein the sample contains both glycated (see Fig. 3, "A_{1c}") and nonglycated (see *e.g.*, Fig. 3, "F") forms of the protein, comprising:

> providing a solid support (see Fig. 1, "separation column 10") capable of binding both the glycated and the non-glycated forms of the protein (see Fig. 3)
>
> changing the pH on the support (see col. 5, line 50, "Isoelectric Focusing Process")
>
> performing first and second measurements indicative of the amount of glycated and/or non-glycated protein (see col. 5, lines 38-40, "[t]he light beam was directed through the capillary column by a bundle of 300, 200 μm o.d. optical fibers"; col. 9, lines 26-27, "sample zones focused inside the capillaries are monitored by CCD camera"); and
>
> determining the amount (see Fig. 3) or ratio (see col. 6, lines 65-66) of glycated protein in the sample from the first and second measurements (see Fig. 3).

Wu & Pawliszyn do not describe a support having "negatively charged groups" and "hydroxyboryl groups." Wu & Pawliszyn do not describe the step of "binding both the glycated protein and the nonglycated protein to the negatively charged groups."

However, Murel describes an IEF technique employing a gradient of borate (see Abstract; col. 6, lines 34-45) and carboxyl-containing polyhydroxyl molecules (see col. 6, lines 5-17). Murel discloses that such polyhydroxyl molecules are subject to relatively alkaline conditions toward the beginning of the IEF gel, where protein sample are introduced into the gel (see col. 5, lines 49-54). Examiner posits that carboxyl-containing polyhydroxyl molecules necessarily have "negatively charged groups" under alkaline conditions, and would be so recognized by persons of ordinary skill. Finally, Murel discloses that such borate-polyhydroxyl complexes have been used in the past to analyze protein mixtures, including hemoglobins (see col. 3, lines 21-23).

It would have been obvious for a person of ordinary skill in the art to modify the method for quantitating a glycated protein, as taught by Wu & Pawliszyn, with a support having "negatively charged groups" and "hydroxyboryl groups" because Murel discovered that "matrices with anchored polyhydroxyl groups, but without borate compounds or other acid, can be pre-manufactured in large numbers using automated equipment; they can be shipped or stored for prolonged periods without the need for drying or freezing, and they can be converted to IEF devices with pH gradients merely by adding borate" (see col. 8, lines 26-32).

With respect to claims 40-42, Wu & Pawliszyn describe a blood sample (see col. 8, line 48).

With respect to claims 43-45, Wu & Pawliszyn describe absorption measurements at 410 nm (see col. 5, lines 36-38)

With respect to claim 46, Murel describes a three carbon alkyl complex of boric acid and glycerol (see col. 6, lines 34-45).

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu & Pawliszyn (US 5,985,121) and Murel (US 4,925,545), as applied *supra* to claim 35, and further in view of Goldstein *et al.*, 20 DIABETES CARE S18 (1997).

Wu & Pawliszyn and Murel describe a method for quantitating a glycated protein as substantially described, *supra*, and incorporated herein.

Wu & Pawliszyn and Murel do not teach the detection of glycated albumin.

However, Goldstein *et al.* teaches that detection of glycated albumin is a useful test for glycemia in diabetes (see p. S20, col. 2).

It would have been obvious for a person of ordinary skill in the art to have performed the methods of quantitation of glycated protein, as taught by Wu & Pawliszyn and Murel, with glycated albumin because Goldstein et al. teaches that measurements of glycated albumin correlate well with measurements of glycated hemoglobin, and that measurement of glycated albumin may be advantageous over measurement of glycated hemoglobin in situations where measurement of glycated hemoglobin in not useful.

Response to Arguments

In prior Office Action, claims 1-21 were rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) in view of various combinations of teaching from Dean *et al.* (US 4,269,605), Sanders (US 4,407,961), May & Richards (GB 2206411 A), and Goldstein *et al.*, 20 DIABETES CARE S18 (1997). In response, Applicants cancel claims 1-21 and provide thorough argumentation to distinguish newly added claims 35-48 over the cited prior art. Applicants' argumentation, as applied to newly added claims 35-48, is fully persuasive and sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/24/06